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Effects of the COVID-19 pandemic on the sexual and mental health of adolescent and adult men who have sex with men and transgender women participating in two PrEP cohort studies in Brazil: COBra study protocol

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ABSTRACT

Introduction The COVID-19 pandemic and its control measures have impacted health and healthcare provision in various levels. Physical distancing measures, for instance, may affect sexual health, impacting access to HIV prevention supplies and changing sexual behaviour, as well as mental health, increasing feelings of unsafety and weakening community support ties. These effects can be worsened among socially marginalised groups, such as men who have sex with men (MSM) and transgender women (TGW). Brazil is among the countries most affected by COVID-19 in the world, where control measures have been inconsistently implemented. We aim to investigate the effects of the COVID-19 pandemic on the sexual and mental health of adolescent and adult MSM and TGW in Brazil.

Methods Convergent mixed-method prospective cohort study, nested in two ongoing HIV pre-exposure prophylaxis (PrEP) cohorts in Brazil, named PrEP1519 and Combina. Participants will be invited to answer, at baseline and after 6 months, a questionnaire about the effects of the COVID-19 pandemic on sexual behaviour, HIV prevention and mental health. Data on HIV infection and sexually transmitted infections (STI) will be collected as part of routine follow-up from the cohorts. Main outcome measures (HIV infection, STI and depression symptoms) will be observed within 12 months after baseline. Sample size is estimated at 426 participants. Complementarily, 50 participants will be invited to in-depth interviews through video calls or interactive voice response, and 20 will be invited to chronicle their lives during the pandemic through digital diaries. Triangulation will be done across qualitative methods and with the quantitative data.

Ethics and dissemination The study was approved by Research Ethics Committees from the Brazilian Universities coordinating the study. Findings will be published in scientific journals and presented at meetings. Informative flyers will be elaborated to communicate study findings to participants and key stakeholders.

Strengths and limitations of this study

- ► The study builds on two ongoing pre-exposure prophylaxis cohorts in Brazil, which allows exploring the effects of the COVID-19 pandemic on the sexual and mental health of a large sample of youth and adults men who have sex with men and transgender women (TGW) as the pandemic unfolds.
- ► Mixed methods will allow a comprehensive approach of how the COVID-19 pandemic affects the web of causation of HIV infection among these groups.
- ► The study uses innovative data collection techniques, such as web-based diaries and reports with photographs.
- ► Remote data collection implies limits, such as not being as aware of participants' facial expressions and body language nor to reach individuals with poor or no access to the internet.
- ► The number of TGW in the cohorts is reduced, which may hinder statistical analysis for this population, depending on their rates of adherence to the present study.

INTRODUCTION

COVID-19 in Brazil

The COVID-19 pandemic is currently a major global health issue.[1] Besides being a health emergency in itself, the pandemic may intensify other health issues and result in a significant setback for the control of other infectious diseases.[2] Health systems placed under considerable strain,[3] along with physical distancing measures[4] can hamper access to healthcare and lead to social isolation, negatively impacting people's physical and mental health.[5]

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In Brazil, the first case of COVID-19 was officially identified on 25 February 2020.[6] On 20 March, the Brazilian Ministry of Health (MoH) declared the existence of community transmission nationwide.[7] By 26 January, Brazil had recorded 8.878.795 cases and 217.831deaths, with a fatality rate of 2.45%,[8] being currently the country with the third highest number of cases and the second in number of deaths globally.[9]

This epidemiological situation is due to a range of factors that may be hampering people's ability to comply with control measures, especially with physical distancing, that is, the practice of staying home as much as possible to prevent the spread of SARS-CoV-2 and of maintaining physical space (at least 6 ft) from others in public areas.

One important factor is the absence of a nationally articulated response to COVID-19. While the country's President has denied the seriousness of the disease, local governments have been implementing control measures not always fully guided by the local epidemiological situation.[10 11] Contradictions and disregard of scientific evidence may be affecting people's perception of the disease and their trust in the information disseminated by authorities, which are key elements to the adoption of protective behaviours.[12] Also, insufficient and belated implementation of emergency social protection measures[11] may be hampering people's ability to comply to physical distancing measures, considering that the country has 66 million people living in poverty and only 40% are formally employed[13]

Potential effects of the COVID-19 outbreak on sexual and mental health

Disease outbreaks can impact sexual health and rights at individual, systemic and societal levels, heightening vulnerabilities of individuals, with immediate and lasting negative consequences for their health,[3] as seen in previous pandemics.[14 15] Thus, attention has been called to the potentially detrimental effects of the COVID-19 pandemic on HIV.[2 16] Prioritising the response to COVID-19 could reduce the availability of HIV-related healthcare delivery, entailing a shortage of supplies and diversion of healthcare providers and financial resources.[3 17 18] Interruptions in HIV treatment and delayed antiretroviral treatment (ART) initiation, along with late diagnosis and limited access to prevention services could contribute to a significant increase in HIV incidence and AIDS-related deaths during and after the COVID-19 crisis.[2 19 20]

In Brazil, the provision of minimum healthcare services during the pandemic has been recommended by the MoH, including HIV testing, treatment and prevention services.[21] However, the urgency to respond to COVID-19-related demands have limited service delivery[22 23] and required adaptations to respect physical distancing measures, often using telehealth.[24 25] Besides, even if services are available, physical distancing recommendations can make people avoid seeking healthcare during the pandemic.[3 17]

The impact of the COVID-19 pandemic on the HIV epidemic may be more severe among groups that are marginalised and disproportionally affected by HIV, such as transgender women (TGW) and men who have sex with men (MSM) in Brazil.[26 27] MSM and TGW may be less willing to disclose sexual health needs during the pandemic to avoid disclosing their sexual orientation and gender identity within the household.[28] Studies[29] have observed an increased difficulty among MSM and TGW in accessing HIV prevention services during the pandemic, disproportionately affecting young people.[30] In Brazil, barriers to picking up pre-exposure prophylaxis (PrEP) refills at health services were the main reason for adult MSM and TGW stopping PrEP during the pandemic.[31]

The COVID-19 pandemic may also impact HIV spread by affecting sexual behaviours. Studies indicate a decrease of casual sex since the pandemic outbreak,[18 31 32] which among youth is associated with increased family supervision and less personal freedom.[18] A study in Australia[33] found that reducing casual sex was the main reason to stop taking PrEP; similarly, in Brazil sexual abstinence was among the main reasons to PrEP interruption among MSM and TGW.[31]

The COVID-19 pandemic may also lead to negative mental health outcomes. Physical distancing measures can lead to social isolation, which is associated with anxiety, depression, post-traumatic stress disorder and stigma, both at immediate and long terms.[4 34 35] In Great Britain, the proportion of adults reporting experiencing some form of depression almost doubled during the implementation of these measures, as compared with the period immediately before it.[36] In the USA, anxiety disorder and depressive disorder increased considerably between April and June 2020, compared with the same period in 2019, being significantly more common in persons aged 18–24 years.[37]

Moreover, the pandemic can hamper individuals' and communities' self-care, that is, their ability to take an active role in protecting their own well-being, promoting and maintaining health, as well as preventing disease and coping with illness and disability.[38] Physical, psychological, spiritual and community support are dimensions of self-care that interrelate and correlate to mental health[38] and that can be impaired by the pandemic. Among MSM and TGW, in particular, physical distancing measures may contribute to psychological suffering by disrupting everyday community ties and social support[39] and may increase their exposure to discrimination and violence in the household, especially among youth[40 41]

STUDY AIMS AND HYPOTHESES

This study aims to investigate the effects of the COVID-19 pandemic on the sexual and mental health of adolescent and adult MSM and TGW participating in two HIV PrEP cohorts in Brazil, with an emphasis on HIV and STI infection.

Secondary aims are to investigate:

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- The social representations[42–46] of the COVID-19 pandemic and the public understanding of its control measures among MSM and TGW.
- The effects of the COVID-19 pandemic on prevention and on HIV and STI incidence among these groups.
- How MSM and TGW manage self-care during physical distancing measures.
- The prevalence of symptoms of depression among MSM and TGW during physical distancing measures.

Our hypotheses are that:

- The COVID-19 pandemic will negatively affect the sexual and mental health of MSM and TGW, with adolescents being more severely affected than adults.
- Public understanding of the scientific evidence of COVID-19 will be affected by the conflicting public messages disseminated in Brazil.
- Social representations of health and disease will be marked by the severity of the COVID-19 pandemic.
- The COVID-19 pandemic may increase the vulnerability of sexual minorities, causing obstacles to accessing healthcare and resulting in increased risk of HIV and STI infection.
- Stressor factors, such as discrimination and violence, are likely to increase during physical distancing measures among MSM and TGW living in hostile family environments.

METHODS

The study will take place in Brazil from June 2020 to December 2021. It adopts a mixed-method,[47] multidisciplinary approach, combining epidemiology, social psychology and medical anthropology.

The study is nested within two existing PrEP cohorts, named PrEP1519 and Combina. PrEP1519 is a demonstration study that aims to evaluate the effectiveness of PrEP use among adolescent MSM and TGW aged 15–19, in three Brazilian cities: Belo Horizonte, Salvador, and São Paulo.[25] Combina is a demonstration study that analyses the effectiveness of PrEP among participants aged 16 years and older. It takes place in six public healthcare services from five Brazilian cities—São Paulo, Ribeirão Preto, Fortaleza, Curitiba and Porto Alegre.[48]

Table 1 shows the estimated HIV prevalence among MSM in these cities in 2016[27] and the COVID-19 cases and deaths recorded until 26 January 2020.[8]

Theoretical approaches

Human rights provide an overarching framework for this study that has informed study tools and methods. Recognising the interdependence of all rights, we afford particular attention to the right to health (including the availability, accessibility, acceptability and quality of health services), privacy and confidentiality, equality and non-discrimination and governmental accountability.[49 50] Aligned with this framework, the concept of vulnerability[51] guided the structuring of the research axes. We considered its three dimensions: structural (eg, stigma, violence, living conditions); programmatic (eg, availability of and access to healthcare); and interpersonal (eg, sexual behaviours, risk perception).

Our theoretical approach is also inspired by the theory of social representations.[42 43] Social representations are defined as a form of common-sense knowledge, with a practical orientation,[44 45] that influence people's conducts.[46 52] People tend to mobilise social representations in contexts of uncertainty to give sense to what is happening and thus adapt their behaviours.[53–55]

Minority stress models[56–58] will also be applied in the analysis to highlight how different stress factors may affect health among youth and adult MSM and TGW during the pandemic.

Study population

The study population consists of MSM and TGW participating in PrEP1519 (aged 15–19 years) and Combina (age ≥16 years). The common inclusion criteria for both cohorts are:

- Having a history of recent risk exposure (condomless sex, history of STI infection, use of PEP) or vulnerability to HIV (eg, drug use, sex work or unstable housing).
- Testing negative for HIV at enrollment visit.
- Accepting to participate in the study.

Table 1 COVID-19 cases and deaths in the general population and estimated HIV prevalence among MSM in the COBra (COVID outbreak in Brazil) study sites

City	COVID-19 cases	COVID-19-related deaths	HIV prevalence estimate, %
São Paulo	454 900	17 004	24.4
Salvador	123 261	3340	8.6
Fortaleza	93 897	4295	10.0
Belo Horizonte	82 714	2182	14.5
Curitiba	76 729	2167	20.2
Porto Alegre	78 790	2075	10.5
Ribeirão Preto	34 017	1041	Data not available

MSM, men who have sex with men.

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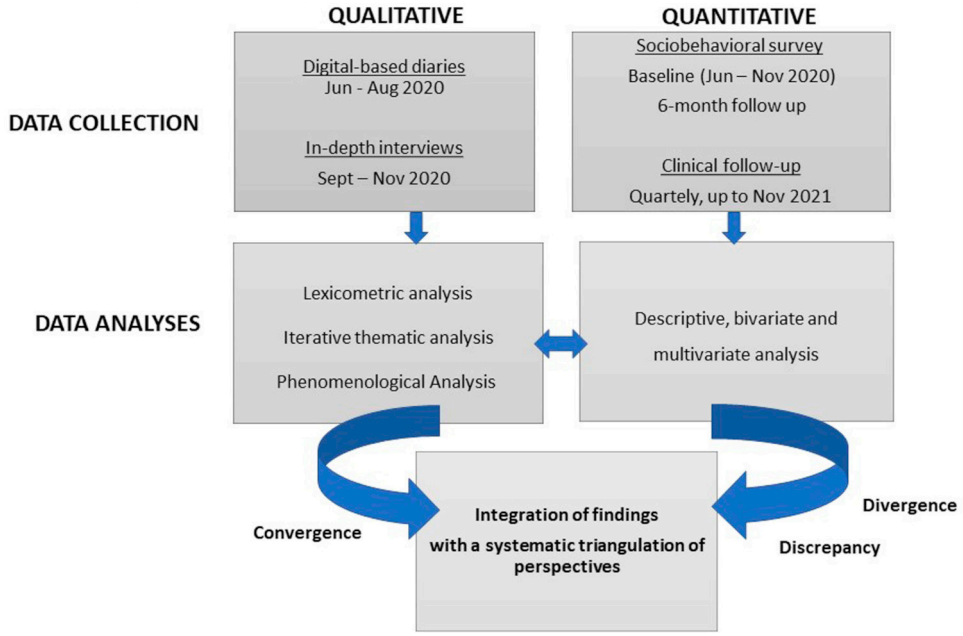

Figure 1 Convergent mixed-methods design: stages and procedures for quantitative and qualitative data collection and analysis at COBra (COVID Outbreak in Brazil) Study.

In the two cohorts, follow-up procedures include quarterly clinical evaluations, counselling and HIV and STI testing. During the physical distancing period, the majority of these consultations and procedures have been done through telehealth, using videoconference, texting and mailing of PrEP pills and HIV self-tests (HIVST) to participants.[25]

Study design

This is a convergent mixed-methods prospective cohort, with independent and concurrent quantitative and qualitative data collection and analysis, and triangulation of findings.

Since part of the data will be collected during COVID-19 physical distancing measures, we will prioritise remote data collection.

Figure 1 provides an overview of data collection, analysis and integration of methods.

Quantitative design

Procedures

All participants enrolled in PrEP1519 and Combina, in all the sites, will be invited by phone calls or text messages to respond to an online questionnaire on their experiences with the pandemic. The baseline questionnaire will be applied during the physical distance measures (between June and November 2020) and repeated after 6 months.

The HIV test result closest to the beginning of physical distancing period will be used as the participant's serological status at baseline. Follow-up will occur for a period of 12 months after baseline to observe the occurrence of HIV and STI infection, using information obtained from regular quarterly PrEP consultations. Based on the follow-up of the cohorts, the rate of responses to online questionnaires and retention is expected to be between 70% and 80%.

Sample size

Sample size was calculated based on the number of participants enrolled in PrEP1519 and Combina cohorts, which corresponds to 891 and 731, respectively. Table 2 shows the profile of participants.

The MSM and TGW sample size for the COBra was estimated on the assumption of a maximum 6% reported behavioural changes (data on non-use of condoms, PEP or PrEP in the last sexual intercourse, in both cohorts) for both groups, during physical distancing period as compared with before, with power of 80% and a significance level of 95%. It corresponds to 426 participants, with the assumption that the proportions of MSM and TGW do not change significantly in relation to the active participants in the cohorts.

Data collection and study variables

Data collection will include variables related to sociodemographic information, COVID-19, sexual health and mental health. These variables are detailed in figure 2.

To prevent missing data, the study and data collection have been carefully planned. Only the essential information will be collected. We will use a friendly report form and will train all the researchers working on data collection.

A management team will be responsible for: verifying compliance with guidelines for research involving human subjects; assessing adherence to the study protocol; and confirming the quality and accuracy of the information collected and entered into the database. Reports will be done as close to real-time as possible during the course

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Table 2 Sociodemographic and sexual behaviour characteristics of PrEP1519 and Combina participants at baseline

	PrEP 15–19		Combina	
Sociodemographics	**n**	**%**	**n**	**%**
Age (years)				
15–17	179	20,09	2	0.3
18–19	712	79,91	14	1.9
20–39	–	–	607	83.0
40–68	–	–	108	14.8
Gender identity or sexual orientation				
MSM	824	92,48	656	89.7
TGW	67	7,52	75	10.3
Skin colour				
Black	351	39,39	56	7.8
Pardo (brown)	253	28,4	206	28.5
White	255	28,62	447	61.9
Asian	22	2,47	10	1.4
Indigenous	10	1,12	3	0.4
Years of study				
<8 years	28	3,14	15	2.1
≥8 years	863	96,86	716	97.9
City				
Belo horizonte	190	21,32	–	–
Curitiba	–	–	26	3.6
Fortaleza	–	–	67	9.2
Porto Alegre	–	–	79	10.8
Ribeirão Preto	–	–	44	6.0
Salvador	288	32,32	–	–
São Paulo	413	46,35	515	70.5
Sexual behaviour				
Sex with casual partner*				
No	228	29,61	59	8.1
Yes	542	70,39	672	91.9
Sex with stable partner				
No	386	49,68	322	44.1
Yes	391	50,32	409	55.9

*PrEP 15–19: in the last 3 months; Combina: in the last 6 months.
MSM, men who have sex with men; PrEP, pre-exposure prophylaxis; TGW, transgender women.

of the study. Preliminary descriptive analyses will be conducted to evaluate frequency distributions and missingness. In case of missing data, study monitors will return to the questionnaires in order to complete the dataset. Remaining cases with missing data will be omitted and complete data analysis will be conducted.

Main outcomes

Three main outcomes will be analysed, namely HIV infection, STI and depressive symptoms:

- For HIV infection, rapid tests will be done as part of the quarterly follow-up routine of both cohorts by trained laboratory technicians. For the estimation of HIV prevalence, the laboratory diagnosis of HIV will follow the algorithm established by the MoH.[59] A two HIV-RT methodology will be used for the detection of HIV antibodies 1 and 2. Preferably, a fourth-generation test will be used as the first HIV-RT and a third-generation test as the second HIV-RT. In the samples with discordant reagent results, the Immunoblot test will be used. If the discrepancy persists, a new blood sample will be drawn to do a conventional laboratory test. For participants who cannot or chose not to attend PrEP consultations during physical distancing period, HIVST will be offered and delivered by mail.[25 60]
- STI diagnosis will be performed during clinical consultations, considering signs and symptoms. We will run quarterly treponemal and non-treponemal laboratory tests for syphilis on blood samples. Gonorrhoea and chlamydia will be investigating every 6 months using qualitative DNA detection through nucleic acid amplification test in urine samples in São Paulo, and research in the oropharynx, urethral and anorectal region in Salvador and Belo Horizonte.
- Finally, depressive symptoms will be investigated through the online questionnaires (baseline and sixth months after), using the Centre for Epidemiological Studies-Depression Scale, which is validate for both adults and adolescents.

Data analysis

Data obtained from questionnaires will be used to create indicators that will allow the categorisation of participants according to the dimensions of interest of the study, with emphasis on: degree of adherence to physical distancing measures, perception of COVID-19, and socioeconomic impact of the pandemic in daily life. Subsequently, we will evaluate the association of these COVID-19 indicators with study intermediate outcomes (interruption of use of HIV services, of HIV prevention methods and greater exposure to HIV) and major outcomes (HIV infection, STI and depression symptoms). This analysis will consider the different phases of the COVID-19 pandemic and control policies adopted. When pertinent, data previously collected during participants' follow-up will be used for comparison. Assessment of the effect of the public statements contrary to physical distancing measures will be stratified according to participants' opinion on the pandemic control measures. Stratification by age groups will also be carried out to analyse outcomes for adolescents and adults.

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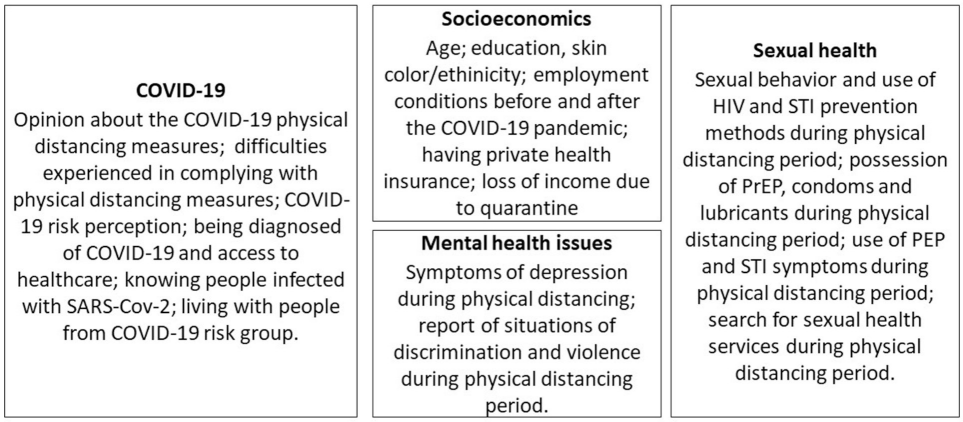

Figure 2 Variables to be explored in the online questionnaire at baseline and after 6 months at COBra (COVID Outbreak in Brazil) Study. PrEP, pre-exposure prophylaxis. STI, sexually transmitted infections.

Statistical analysis

Descriptive analysis will be carried out and frequency tables and figures will be produced to verify the distribution of the study variables. Measures of central tendency and variability will be calculated for the quantitative variables. Bivariate analysis will be carried out for the joint distribution of sociodemographic, socioeconomic, and sexual behaviour variables and outcome variables of interest.

Different regression models will be used to estimate associations between predictors and outcome variables, according to the different analytical strategies for the study outcomes. Therefore, OR, prevalence ratios and HRs will be estimated to investigate association between predictors and outcomes using, respectively, logistic, Poisson and Cox regression models.

Recognising the important differences existing between MSM and TGW, quantitative analyses will be carried out separately for each of these groups as much as possible. A lower participation of TGW in the study may compromise certain statistical analyses for this population, so we will apply analytical strategies specific to studies with small samples and will triangulate findings with the qualitative data.

Qualitative design

Procedures

A comprehensive approach[61] using a mix of qualitative techniques will be adopted[61–63] to enable a deep understanding of: (1) participants' social representations of the COVID-19 pandemic and their understandings of control measures, (2) participants' self-care practices during physical distancing period and (3) effects of the COVID-19 pandemic on HIV prevention behaviours.

Data collection

Techniques will include semistructured interviews, field work notes from researchers' diaries, and participants digital-based diaries.

PrEP1519 participants will be invited to chronicle their lives during physical distancing measures (June–August 2020) using digital-based diaries, a technique that can enhance participation[64] and is adequate to investigate sensitive topics.[65] These narratives will allow a longitudinal approach and a reduced recall bias. The diaries will be audio and written recorded, according to participants' choice. They will also be allowed to complement their reports with photographs that represent their lives during the pandemic. This can increase research participation by overcoming limitations related to limited literacy, and also because photographs are a cultural practice highly integrated in youths' participation in social networks.[66] In order to protect their confidentiality, pictures must not reveal their identity.

Interviews will be conducted by trained and experienced fieldwork researchers, through video calls or interactive voice response, according to participant's choice, to ensure their feasibility during physical distancing measures (September–November 2020). They will be audio recorded with participants' consent, and guided by a semistructured script (online supplemental appendix 1) covering the following themes, all relating to experiences during physical distancing measures: social representations of COVID-19; participants' self-care practices; sexual health and behaviour; mental health; and HIV prevention.

Participants

We will seek to include an equal number of TGW and MSM. For the interviews, we will invite at least 50 participants (25 TGW and 25 MSM) from the two cohorts in the sites of São Paulo and Salvador. For the diaries, at least 20 young MSM and TGW enrolled on PrEP1519 will be invited to participate, also from the two aforementioned cities.

Data analysis

Audiorecorded data from interviews and diaries will be transcribed verbatim for analysis. Lexicometric, thematic and phenomenological data analysis will be run independently and concurrently and will be triangulated for interpretation, as detailed below. TGW and MSM will be analysed separately.

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Statistical textual analysis

We will do a statistical textual analysis using IraMuTeQ.[67 68] This software converts textual data into numerical data to calculate the frequency of words and their relations[69] and performs hierarchical clustering through correspondence factorial analysis.[70] This allows identifying the underlying structure of the dataset and forming clusters[71] based on the lexicon used by the interviewees to represent and communicate the phenomenon under analysis. Also, by adding variables that qualify the interviewees' speech (eg, age, sexual orientation, gender identity), the software allows the identification of particularities in the lexicon of different groups, making this technique particularly interesting to studying social representations.[72] Additionally, the lexicometric analysis contributes to reducing the interference of the researchers' subjectivity in the categorisation of data.[72]

Thematic analysis

Data from interviews and diaries will also be subjected to iterative thematic analysis.[73] We will use iterative categorisation to: systematically order and sort coded data, and to support the analysis by prioritising codes that will help identify reiteration, complementarity and discrepancy between codes.[73]

A codebook will be developed according to the following steps[74]: reading of transcriptions to ensure familiarisation with their content and stablish initial codes to raw data (inductive approach); development of new codes as additional themes emerge in the data (deductive approach) until code saturation is achieved; and labelling, description, definition and illustration of codes by raw data. Codes may be complemented with themes identified in the statistical textual analysis.

For coding visual data, a text log to describe the picture and the coded area will be systematically created. The analysis of this material will be guided by principles of phenomenological analysis of photographs.[75]

NVivo software will be used to assist coding and analytical processes,[76 77] with the same codebook being applied to both textual and visual data.[78]

Data Triangulation

We will apply a systematic triangulation of perspectives,[79] with triangulation being done across qualitative methods as well as with the quantitative data.

The integration of methods will occur during the interpretation stage by comparing findings to identify convergence, discrepancy and divergence[80] for the following themes: sexual behaviour, HIV prevention, mental health and social representations of COVID-19.

By doing so, we recognise that the complexity of the issues under study requires a comprehensive approach, in which different methodologies—that express different epistemological positions—enable opportunities for either corroboration or identification of areas where deeper contextual analysis is required to address different levels and qualities of the social phenomena,[78] thus creating new knowledge.

DISCUSSION

This study will seek to identify HIV prevention patterns, use of health services, mental health and self-care during the COVID-19 pandemic among youth and adult MSM and TGW. This will allow to assess the effects of the pandemic on the incidence of HIV, STI and depression among these groups and contribute to identifying factors associated with such effects. The convergent mixed-method approach will allow not only to measure these effects, but to build a more comprehensive understanding about them.

TGW and MSM may suffer a deeper impact from the COVID-19 pandemic when compared with the general population, and can be hard to reach. By building on existing HIV prevention cohorts, including the only PrEP demonstration study of adolescent MSM and TGW in Latin America (PrEP1519), we will be able to reach these populations in different Brazilian cities. This diversification of age groups and study sites will contribute for more consistent and comprehensive results.

The study results may contribute to the design of sexual and mental health policies that are better suited to TGW's and MSM's needs. Particularly, it may allow to identify strategies to ensure HIV prevention delivery, along with comprehensive sexual and mental healthcare, during situations of sanitary crisis, by combining telehealth with traditional service organisation. This will enable adaptations of service delivery in the involved cohorts and may contribute to adaptation of services in other contexts.

This study has limitations that need to be considered. First, our results may represent a more optimistic scenario than what would be found among the general population of TGW and MSM. Being included in demonstration studies—and, therefore, in health services—participants are likely to have a greater degree of information and more favourable social conditions than other MSM and TGW. Second, the use of internet-based data collection techniques may impede the participation of those who have precarious or no internet access, and who may be precisely the most vulnerable to the harmful effects of the COVID-19 pandemic. Third, the depth of qualitative data may be impaired by the challenges inherent in remote data collection, such as not being aware of participants' facial expressions and body language. Finally, certain statistical analysis regarding TGW may have limited validity, given potential difficulties to recruit this group.

ETHICS AND DISSEMINATION

PrEP1519 and Combina were approved by the Ethics Research Committee (ERC) from the Universities coordinating the studies. Combina was also approved by the Brazilian National Ethics Research Commission (CONEP) and PrEP15-9 by the WHO's ERC. For COBra study, a notification of substantial amendments was submitted to and approved by all the ERCs that had previously approved PrEP15-19 and Combina.

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Results will be published in peer-reviewed journals and presented at scientific meetings, assuring transparency of data and anonymity of participants. Complementarily, informative flyers will be elaborated to communicate the study findings to participants, to key stakeholders (MoH, local health authorities, PrEP1519 and Combina staff), aiming to inform how services can better respond to the needs of participants during a sanitary crisis. This material will also be made available at the PrEP1519 and Combina websites.

PATIENT AND PUBLIC INVOLVEMENT

This study is strongly oriented by lessons learnt from patients during the implementation of PrEP1519 and Combina. Access to sexual and mental healthcare have been shown to be a central need among participants, and assuring access and continuity of care has often been challenging.

Patients were not directly involved in the design of the COBra protocol because it was developed during the COVID-19 crisis, with time constrains and physical distancing measures preventing a wider community involvement. It is worth noticing, though, that PrEP1519 has a strong community participation, with youth TGW and MSM working directly in recruitment and retainment activities.

To assure dissemination of findings to participants and communities, we will develop informative flyers with voluntary participants, to be made available in all the channels used by the research teams to communicate with participants (eg, cohorts' websites, WhatsApp groups and Instagram).

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